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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,294	10/02/2001	Gary K. Michelson	101.0070-02000	2538
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MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632				
			EXAMINER PRIDDY, MICHAEL B	
			ART UNIT 3732	PAPER NUMBER

DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,294

Applicant(s)

MICHELSON, GARY K.

Examiner

Michael B Priddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 91-135 and 139-145 is/are pending in the application.
- 4a) Of the above claim(s) 96, 102-108, 111-113, 116, 117, 144 and 145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 133-135 and 143 is/are allowed.
- 6) ☐ Claim(s) 91, 93-95, 97-101, 109, 110, 114, 115, 118-131 and 139-142 is/are rejected.
- 7) ☐ Claim(s) 92 and 132 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Claims 102-108, 111-113, 116, 117, 144 and 145 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7. Applicant's traversal was on the grounds that the requirement did not identify any linking claims. The Examiner contends that the paragraph Applicant has requested be included in this Office Action is inappropriate for the present situation. Species claims are linked by genus claims. A genus claim (a generic claim) is a claim that is readable on *all* the claimed species. The Examiner agrees with Applicant that independent claims 91, 130 and 133 are generic to all the species of the present application and therefore link all claimed species. The following paragraph was included in the Restriction Requirement mailed 05/30/2003 but will be repeated here for clarification.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claim Rejections - 35 USC § 112 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 125 and 126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 125 apparently requires the screw of claim 91 to further comprise bioresorbable plastics. Nowhere has the specification made it clear how a screw of these materials is to be constructed. It is therefore the Examiner's belief that the bioresorbable plastics are intended to be a substitute material for the cortical bone recited by claim 91. The claims have been treated as such with respect to the prior art.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 95 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 95 recites the limitation "said head" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 91, 93-95, 97, 109, 110, 115, 119, 121-123, 130 and 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. (U.S. 6,045,554) in view of Greenslade (U.S. 5,088,869). Grooms et al. teaches a screw formed of cortical bone for use in the human body (see Exhibit A), said screw comprising a leading end, a trailing end opposite said leading end, and a shaft therebetween, said shaft having a mid-longitudinal axis, a length and a thread extending from said shaft along at least a portion of its length; said thread configured to cooperatively engage at least a portion of the screw hole of an implant so as to prevent said screw from linear motion along the mid-longitudinal axis of said shaft in a direction opposite to the direction of insertion when said screw is threaded through a screw hole to attach the implant to a bone portion of the human body; said screw being formed substantially of cortical bone of a single thickness ("cortical sections are removed from linear aspects of the femur or from the anterior cortex of the tibia"-- column 4, lines 25&26). As set forth in lines 34-36 of column 3, "the head may have a machined, recessed Allen-wrench, star headed driver, Phillips head or slotted head purchase for torque application."

Grooms et al. therefore teaches all of the limitations of the present invention except said shaft having a cross section transverse to said mid-longitudinal axis through

said thread having a concavely arcuate portion and a convexedly arcuate portion opposite said concavely arcuate portion, said cross section bisecting a rotation of said thread and an enlarged portion proximate said trailing end with a dimension transverse to the mid-longitudinal axis of said shaft greater than said outer diameter of said thread, said enlarged portion configured to prevent said trailing end from passing through the screw hole in the implant; wherein said enlarged portion forms a lip.

Greenslade teaches a thread rolling screw having a shaft 17 with a mid-longitudinal axis, said shaft having a cross section transverse to said mid-longitudinal axis through thread 21b having a concavely arcuate portion 27 and a convexedly arcuate portion 25 opposite said concavely arcuate portion 27, said cross section bisecting a rotation of said thread 21b; said screw further comprises an enlarged portion proximate said trailing end with a dimension transverse to the mid-longitudinal axis of said shaft greater than said outer diameter of said thread, said enlarged portion configured to prevent said trailing end from passing through the screw hole in the implant wherein said enlarged portion forms a lip (see marked up copy of Fig. 1 in Exhibit B). Recessed areas on the crest of screw threads allow for reduced torque while installing the fastener (column 1). It would have been obvious to one of ordinary skill in the art at the time of the present invention to form concavely arcuate portions or relieved areas on the thread of Grooms et al. to reduce the torque required while installing the fastener in the human body.

Claims 130 and 131 are being interpreted as product-by-process claims and it should be noted that "even though product-by-process claims are limited by and defined

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by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) The present claims are believed met by the structure taught by the combination of Grooms et al. and Greenslade.

Claims 98-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. and Greensdale as applied to claims 91 and 94 above, and further in view of Huebner (U.S. 6,030,162). Grooms et al. and Greensdale teach all of the limitations of the present invention except said trailing end including a second thread having a different thread pitch than said thread along said shaft; wherein the thread pitch of said second thread is similar to a metal screw pitch and the thread pitch of said thread along said shaft is similar to a wood screw pitch.

Huebner teaches an axial tension screw having a trailing end said trailing end having a second thread 826 having a different thread pitch than said thread 824 along said shaft; wherein the thread pitch of said second thread 826 is similar to a metal screw pitch and the thread pitch of said thread 824 along said shaft is similar to a wood screw pitch. Such a thread configuration allows that "as the screw moves forward, axial compression is generated along the length of the root" which will result in "bone fragments (are) being drawn together". It would have been obvious to one of ordinary

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skill in the art at the time of the present invention to modify the thread of the combination such that the pitch of the thread along the shaft was less than that of the second thread to produce axial compression to draw fragments of bone together.

Claim 118 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. and Greenslade as applied to claim 94 above, and further in view of Schenk (U.S. 6,048,344). Grooms et al. and Greenslade teach all of the limitations of the present invention except a tip of said leading end is fluted.

Schenk teaches a bone screw 60 having flutes 70 at its distal tip to permit the screw to be inserted without pre-drilling or tapping. It would have been obvious to one of ordinary skill in the art at the time of the present invention to provide flutes on the tip of the screw of the combination of Grooms et al. and Greenslade to allow insertion of the screw without pre-drilling or tapping.

Claim 120 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. as applied to claim 94 above, and further in view of the following. Grooms et al. discloses the claimed invention except for the cortical bone being obtained from a generally intramembraneously formed cortical bone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the screw of Grooms et al. of cortical bone obtained from a generally intramembraneously formed cortical bone, since it has been held to be within the

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general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 124, 127-129 and 139-142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. and Greenslade as applied to claims 91 and 94 above, and further in view of Klardie et al. (U.S. 6,048,204). Grooms et al. and Greenslade teach all of the limitations of the present invention except the screw being comprised of hydroxyapatite.

Klardie et al. teaches a self tapping screw type dental implant formed of titanium alloys or pure titanium but which may be coated with a material to facilitate healing and/or bone growth. "The outer surfaces of the implant may be coated with hydroxyapatite." (lines 32-34 of column 6) It would have been obvious to one of skill in the art to treat or coat the screw of the combination taught by Grooms et al. and Greenslade with hydroxyapatite to facilitate healing and/or bone growth.

Claims 125 and 126 are rejected under 35 U.S.C. 102(b) as being anticipated by Gogolewski et al. (U.S. 5,275,601). Gogolewski et al. teaches a screw 10 formed of resorbable polymers as set forth in Table 1 in column 4 for use in the human body, said screw 10 comprising: a leading end 2, a trailing end 4 opposite said leading end 2, and a shaft 1 therebetween, said shaft 1 having a mid-longitudinal axis a length and a thread 5 extending from said shaft 1 along at least a portion of its length.

Gogolewski et al. therefore teaches all of the limitations of the present invention except said shaft having a cross section transverse to said mid-longitudinal axis, said shaft having a cross section transverse to said mid-longitudinal axis through said thread having a concavely arcuate portion and a convexedly arcuate portion opposite said concavely arcuate portion, said cross section bisecting a rotation of said thread.

Greenslade teaches a thread rolling screw having a shaft 17 with a mid-longitudinal axis, said shaft having a cross section transverse to said mid-longitudinal axis through thread 21b having a concavely arcuate portion 27 and a convexedly arcuate portion 25 opposite said concavely arcuate portion 27, said cross section bisecting a rotation of said thread 21b. Recessed areas on the crest of screw threads allow for reduced torque while installing the fastener. It would have been obvious to one of ordinary skill in the art at the time of the present invention to form concavely arcuate portions or relieved areas on the thread of Gogolewski et al. to reduce the torque required while installing the fastener in the human body.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 91-95, 97-101, 109, 110, 114, 115, 118-129 and 139-142 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-8, 16-18, 21, 22, 25-34 and 139-142 of copending Application No. 09/970,241 in view of Greenslade. Application No. 09/970,241 teaches all of the limitations of the present invention except "said shaft having a cross section transverse to said mid-longitudinal axis through said thread having a concavely arcuate portion and a convexedly arcuate portion opposite said concavely arcuate portion, said cross section bisecting a rotation of said thread." Greenslade teaches a thread rolling screw having a shaft 17 with a mid-longitudinal axis, said shaft having a cross section transverse to said mid-longitudinal axis through thread 21b having a concavely arcuate portion 27 and a convexedly arcuate portion 25 opposite said concavely arcuate portion 27, said cross section bisecting a rotation of said thread 21b. Recessed areas on the crest of screw threads allow for reduced torque while installing the fastener. It would have been obvious to one of ordinary skill in the art at the time of the present invention to form concavely arcuate portions or relieved areas on the thread of Grooms et al. to reduce the torque required while installing the fastener in the human body.

This is a provisional obviousness-type double patenting rejection.

Allowable Subject Matter

Claims 92 and 132 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 133-135 and 143 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Michael B. Priddy

Michael B. Priddy
October 7, 2003

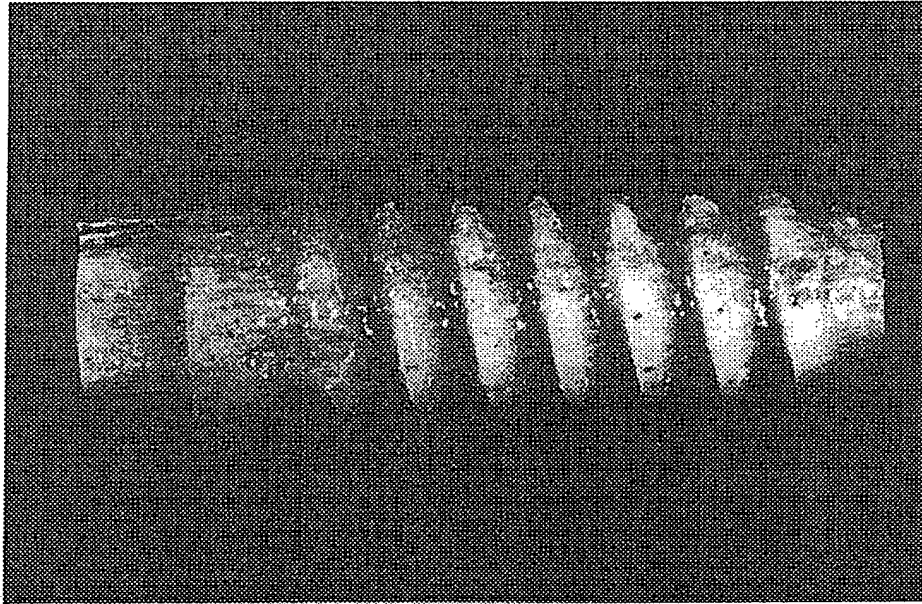


FIGURE 1A

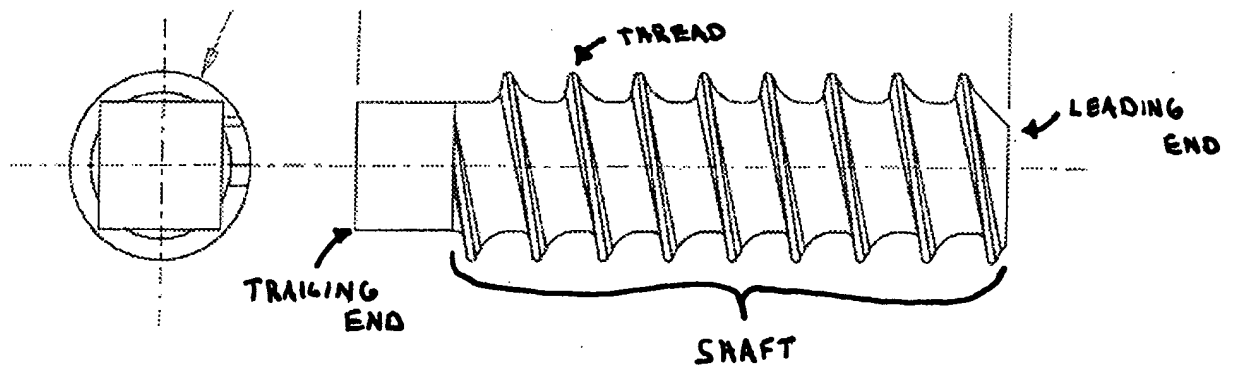


FIGURE 1B

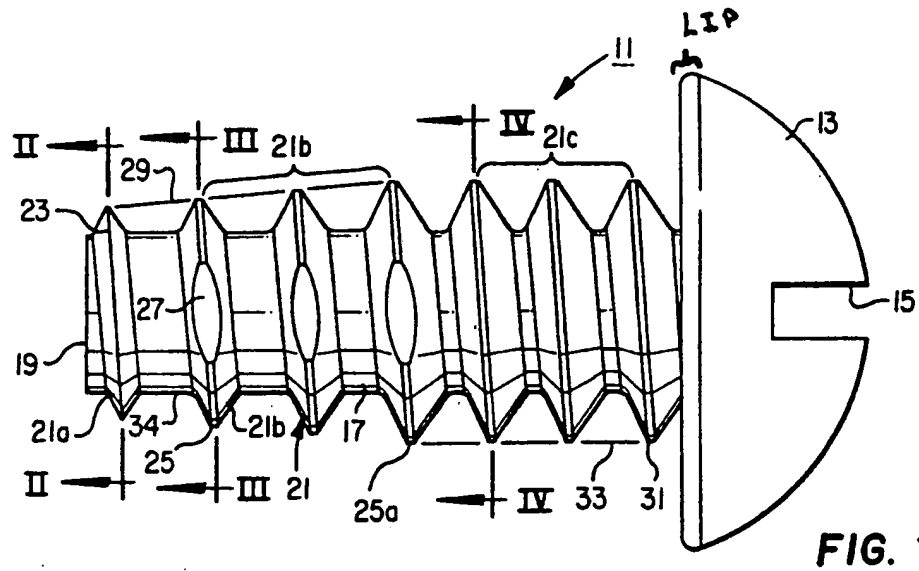


FIG. 1

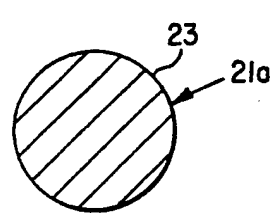


FIG. 2

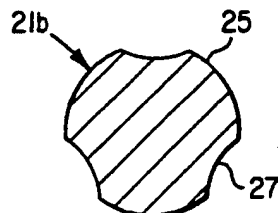


FIG. 3

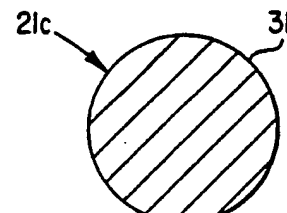


FIG. 4

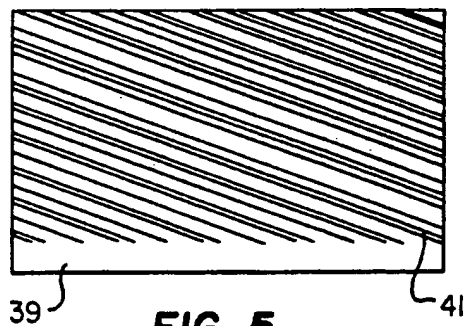


FIG. 5

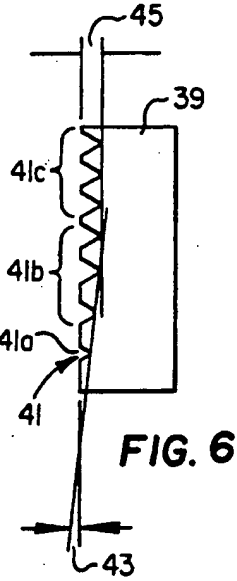


FIG. 6

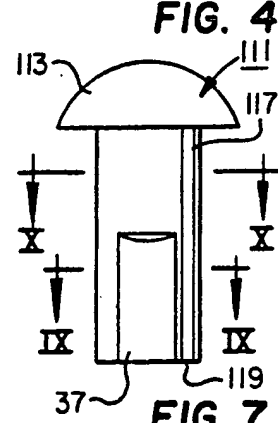


FIG. 7

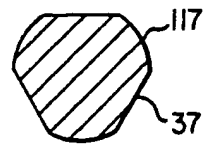


FIG. 9

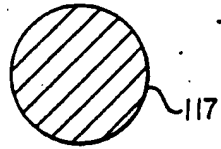


FIG. 10

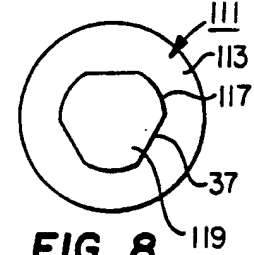


FIG. 8